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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,597	12/19/2000	Bruce J. Barclay	VASC 1020-1	3762

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/740,597

Applicant(s)

BARCLAY ET AL.

Ch

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 6,8,10,15 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9,11-14,16-25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4,5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Location of drug on the stent device.

Species I: Fig. 5D, covering/matrix with drug.

Species II: Fig. 5E, drug covers porous covering.

Species III: Fig. 5F, drug is between covering and stent.

Additional species:

Protective Layer

Species A: biodegradable material.

Species B: removable sheath.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by

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37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with James Hann on 9/17/02 a provisional election was made with traverse to prosecute the invention of Species III and A, claims 1-5,7,9,11-14,16-25,27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6,8,10,15,26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5,7,9,11-14,16-25,27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 1,20,21, "a stent subassembly" is defined as a "porous covering, a drug and stent body." However, on page 4, lines 9 and 10, "a stent subassembly" is recited, but there is no recitation as to what defines a "stent subassembly." The specification mentions a "protective layer" in lines 8 and 9 which *can be included* to be part of the "stent subassembly" since there is no clear definition of what applicant intends to be the "stent subassembly."

Regarding claim 27, the step of "removing the stent subassembly from the patient **following** the permitting step" is not enabled by the disclosure. On page 4, lines 8-11 and also on page 8 of the specification it recites a "protective material is *removed*" to permit the drug to be administered. There is no recitation that the drug is permitted to be released, and **then** any material is removed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1,3-5,7,9, 21,23,27 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwin (6358276). Figs. 1,4 and 11a-c all show a coiled stent body. Edwin discloses that the stent is made from a metal, such as nitinol, col. 5, lines 8-9. Edwin also discloses delivering a drug to a site with a stent having a porous covering thereon with the drug between the stent and PTFE covering, col. 2 lines 50-54. Edwin also discloses means for delaying the drug to be released, col. 5, lines 14-16.

Claims 1,3-5,7,9,11-14,16-18,21-25,27 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (5873904). Figs. 11 and 15 show a coiled body stent. Ragheb et al. disclose a stent that has a drug layer with a porous covering thereon, col. 4, lines 23-32. The stent can be made from metal, such as nickel-titanium, col. 3, lines 58-59. Drugs that can be delivered via the stent include taxol and heparin, col. 11, lines 1-11, 63-65. The porous polymer covering the drug can be PTFE, col. 5, lines 43,44,50,51. Ragheb also discloses the bioactive material or drugs can be microencapsulated, col. 19, lines 60-63. Ragheb additionally discloses the covered stent can comprise an additional protective layer or porous layer, col. 14, lines 53-54. The outer porous

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layer can be a polymer that is biodegradable, col. 13, lines 33-44. It is inherent that the method of Ragheb includes the step of waiting for the protective material to release the drug after degradation because Ragheb is interested in controlling release of therapeutic material, col. 2, lines 59-65 and also col. 14, lines 59-61.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. ('904) in view of Kropf (4760849). Ragheb is explained supra. However, Ragheb does not disclose a stent body that has spaced-apart parallel side elements joined by connector elements. Kropf teaches a stent body with spaced-apart parallel side elements joined by connector elements, Fig. 5. It would have been obvious to one of ordinary skill in the art to use the stent design of Kropf in the device of Ragheb et al. in order to provide a stent with greater coverage area.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al. ('904) in view of Wright et al. (6273913). Ragheb is explained supra. However, Ragheb does not disclose a stent that uses the drug rapamycin. Ragheb does disclose the use of anti-inflammatory drugs, col. 4,

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lines 55-65. Wright et al. teach that rapamycin is an anti-inflammatory drug, col. 5, lines 22-24. Rapamycin is used with a stent, see col. 6, lines 25-28, 41-45 of Wright. It would have been obvious to one of ordinary skill in the art to substitute anti-inflammatory drugs and use rapamycin as taught by Wright with the stent device of Ragheb in order to reduce restenosis.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Derbyshire (5007926) shows a stent with a body of spaced-apart parallel side elements joined by connector elements.

Loomis (6028164) discloses that stents can be implanted with compositions that have controlled release of anti-inflammatory agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino


Bruce Snow

TC 3700, AU 3738 September 18, 2002

Primary Examiner

